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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,472	12/19/2005	Signe M. Christensen	22460-003US1 / 1015US2	4416
26161 7590 11/09/2007 FISH & RICHARDSON PC			EXAMINER	
P.O. BOX 1022	2	WOLLENBERGER, LOUIS V		
MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
•			1635	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/535,472	CHRISTENSEN ET AL.			
		Examiner	Art Unit			
		Louis V. Wollenberger	1635			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠)⊠ Responsive to communication(s) filed on <u>14 September 2007</u> .					
, —	This action is FINAL . 2b)⊠ This action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposit	ion of Claims					
 4) Claim(s) 43-68 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 43-68 are subject to restriction and/or election requirement. 						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority (under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachmer		4) 🔲 Interview Summar	v (PTO-413)			
2) Notice 3) Infor	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	Paper No(s)/Mail E 5) Notice of Informal 6) Other:	Date			

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NOTICE OF NON-RESPONSIVE AMENDMENT/REPLY

Amendments to the claims

Applicant's amendment to the claims is acknowledged. With entry of the amendment filed 9/14/2007, Claims 43-68 are pending and remain subject to the restriction mailed 5/1/2007 for the reasons set forth therein.

Election/Restrictions

Applicant's election without traverse of Group III, claim(s) 1–9, drawn to a pharmaceutical composition comprising a therapeutically active antisense oligonucleotide comprising at least two consecutive <u>alpha-L-oxy-LNAs</u> or derivatives thereof, in the reply filed on 9/14/2007 is acknowledged. Also acknowledged is applicant's election of a single construct, identified in the remarks as:

TaGaCagsTascsastscsgsTascsTaTaT) as depicted in Table 8 on page 38 of WO2004/046160.

However, the elections are not fully responsive to the Requirement mailed 5/1/2007 for the following two reasons.

1. As explained in the foregoing Requirement, a complete reply must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. This includes new and subsequently added claims. In the instant case, the elected Claims 1-9 are no longer pending and applicant has not specifically identified which of new claims 43-68 read on the elected invention.

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2. While applicant has elected a single construct (see image above), this election is not pertinent to the subject matter now claimed in 43-68 or to that specifically recited in original claims 1-9. The elected construct, shown above, was never recited in claims 1-9 and is not currently recited in any of new claims 43-68. What is needed is a specific election of a single composition, i.e., embodiment, as now claimed. Applicant's election of the construct above is not relevant to, nor does it help the examiner specifically identify which of the many different embodiments now recited in the claims applicant wishes to have examined on the merits.

As previously explained in the Requirement mailed 5/1/2007 (pp. 5-6), the instant application claims a multitude of different compositions and nucleic acid molecules, too numerous to categorize or identify. For example, claim 43 recites at least two alternative sequences of the order ABC or CBA, wherein B may comprise, along with at least one LNA, either erythro- or ribo-pentofuranosyl. Applicant must elect one order and either erythro- or ribo-. The alternatives recited in claim 43 represent different special technical features; therefore the compositions thereof lack unity of invention. Applicant must elect a single structurally distinct molecule from claim 43, as recited in claim 43. Claim 45 claims one such embodiment, but not the other.

Applicant should then proceed to claim 44, 45, 46, and so on, down the line, up to and including claim 68, selecting a single alternative in each claim where multiple alternatives are recited. The election should not include mutually exclusive features.

Further examples include claim 46, which recites multiple distinct alternative units for inclusion in the A and C sections, and further provides for either alpha or beta configurations.

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Therefore, multiple different compositions and special technical features are recited. Applicant must elect one (1) for prosecution on the merits.

Claims 54-56 add yet further alternatives. Applicant must elect one value. See also, in particular, claims 64 and 68. Where multiple different lengths of the molecule are recited such as claim 59, applicant must elect one.

Applicant should review each claim for compliance with the restriction to a single inventive concept, as required by the Action mailed 5/1/07. The election of more than one alternative molecule and/or composition, or the election of mutually exclusive features will be treated as non-responsive. Furthermore, the election must be directed to the subject matter as claimed.

Note: this is not a species election but an election of a single inventive concept.

Applicant is advised that a reply to this requirement must include an identification of the inventions that is elected consonant with this requirement, and a listing of all claims readable thereon, <u>including any claims subsequently added</u>. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is advised that linking claim practice is in effect. See MPEP 809.03. Upon election of a single molecule/composition from claim 43, claim 43 will be treated as a linking claim, linking those inventions of claims 44-68 that are embraced by, and therefore subgeneric to the molecule/composition elected from claim 43. This pertains only to those compositions that are embraced by the elected embodiment. Upon the indication of allowability of a linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking

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claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPO 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/ Art Unit 1635 November 3, 2007